



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,348	11/28/2001	Thomas Kragh Christensen	NN-40 (P200001223)	1963

7590 06/29/2005

Reza Green Esq
Nova Nordisk Pharmaceuticals Inc
100 College Road West
Princeton, NJ 08040

EXAMINER

SMITH, JEFFREY A

ART UNIT	PAPER NUMBER
----------	--------------

3625

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,348

Applicant(s)

CHRISTENSEN ET AL.

Examiner

Jeffrey A. Smith

Art Unit

3625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/28/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 3625

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It not clear in what sense the method according to claim 1 is "used". "Use" may come in the form of:

a) a process of using (i.e. manipulating) a product or apparatus; or

b) a process of making (i.e. manufacturing) an article of manufacture or apparatus.

The recitation of "The use of a method" in claim 16 gives rise to ambiguity in:

1) how (if construed to be a method of use (i.e. manipulation) consistent with the method of use (i.e. manipulation) recited in claim 1) it distinguishes differently from the recitation of the claim 1 "method" alone; and

2) how it may be interpreted to encompass, in addition to a process of using (i.e. manipulating) an apparatus (i.e. the apparatus defined in claim 1), a process of making (i.e. manufacturing) an article of manufacture (e.g. a program product embodying code or instructions for executing the method according to claim 1).

A discussion of each point of ambiguity identified above follows.

Regarding point 1

"[U]se of the method according to claim 1" may be by way of actual performance of the steps of the method according to claim 1. In this case, it is not clear how one "uses" the steps of the method according to claim 1 in a manner which differs materially from the manner of performing the recited steps

Art Unit: 3625

according to the method of claim 1 themselves. That is, it is unclear how one "uses" or "manipulates" the apparatus defined by claim 1 in a manner which differs materially (given the further recitation of "use" in claim 16) from the manner in which one "uses" or "manipulates" the apparatus defined by claim 1 given the steps recited in claim 1 alone.

It is noted that the recitation in claim 16 "for customising a medical application device" appears to be an attempt to further modify the intent of the "use", however, this recitation does not serve to clarify the intent of the term "use" because it does not provide: a) an active step which modifies the recited "use"; b) a further active step of the method according to claim 1; or c) a further limitation to the product already recited in the method according to claim 1. Accordingly, such recitation does not move to distinguish the "use" of the method according to claim 1 (as recited in claim 16) from the method according to claim 1 itself (as recited in claim 1).

Regarding point 2

In addition to the interpretation provided above that "[U]se of the method according to claim 1" may be by way of actual performance of the steps of the method according to claim

Art Unit: 3625

1, "[U]se of the method according to claim 1" may also be by way of the performance of steps (other than the recited steps of the method according to claim 1) to tangibly embody the method according to claim 1 into an article of manufacture. For example, it is conceivable that a "use of the method according to claim 1" may constitute a process which takes steps to embody the method according to claim 1 in the form of computer-executable code or instructions onto a computer-readable medium--thereby defining a process of making an article of manufacture in the form of a program product. According to this interpretation, the method according to claim 1 need not actually be performed, but the method according to claim 1 is still considered "used" in that it is embodied as code or instructions for later execution by a computer. As a result, it is not clear in what sense the term "use" is being applied. And, in the event that the term "use" is being applied in the sense that it is intended to invoke a process of making an article of manufacture, it is not clear in what manner the steps recited according to the method of claim 1 are incorporated in the "use" recited in claim 16 (i.e. as being actually performed or as being merely tangibly embodied, as for example, into a computer-readable medium).

Art Unit: 3625

Moreover, and in the event that the term "use" is being applied to invoke a method of making an article of manufacture tangibly embodying the method according to claim 1, the Examiner notes that such intent gives rise to an issue under the same paragraph of this statute regarding the propriety of claim 16 as depending from claim 1. That is, claim 16 may be considered as improperly depending from claim 1--if claim 16 (i.e. "use of the method according to claim 1") can be infringed without actually infringing claim 1 (i.e. performing the recited steps of the method according to claim 1).

For examination purposes claim 16 has been interpreted as follows:

--16. The method according to claim 1, characterized in that the product is a medical application device.--.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 3625

Claims 1-7, 16, 17, and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As an initial matter, the United States Constitution under Art. I, §8, cl. 8 gave Congress the power to "[p]romote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries". In carrying out this power, Congress authorized under 35 U.S.C. §101 a grant of a patent to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition or matter, or any new and useful improvement thereof." Therefore, a fundamental premise is that a patent is a statutorily created vehicle for Congress to confer an exclusive right to the inventors for "inventions" that promote the progress of "science and the useful arts". The phrase "technological arts" has been created and used by the courts to offer another view of the term "useful arts". See *In re Musgrave*, 167 USPQ (BNA) 280 (CCPA 1970). Hence, the first test of whether an invention is eligible for a patent is to determine if the invention is within the "technological arts".

Further, despite the express language of §101, several judicially created exceptions have been established to exclude

Art Unit: 3625

certain subject matter as being patentable subject matter covered by §101. These exceptions include "laws of nature", "natural phenomena", and "abstract ideas". See *Diamond v. Diehr*, 450, U.S. 175, 185, 209 USPQ (BNA) 1, 7 (1981). However, courts have found that even if an invention incorporates abstract ideas, such as mathematical algorithms, the invention may nevertheless be statutory subject matter if the invention as a whole produces a "useful, concrete and tangible result." See *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* 149 F.3d 1368, 1973, 47 USPQ2d (BNA) 1596 (Fed. Cir. 1998).

This "two prong" test was evident when the Court of Customs and Patent Appeals (CCPA) decided an appeal from the Board of Patent Appeals and Interferences (BPAI). See *In re Toma*, 197 USPQ (BNA) 852 (CCPA 1978). In *Toma*, the court held that the recited mathematical algorithm did not render the claim as a whole non-statutory using the Freeman-Walter-Abele test as applied to *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ (BNA) 673 (1972). Additionally, the court decided separately on the issue of the "technological arts". The court developed a "technological arts" analysis:

The "technological" or "useful" arts inquiry must focus on whether the claimed subject matter...is statutory, not on whether the product of the claimed subject matter...is statutory, not on whether the prior art which the claimed subject matter purports to

Art Unit: 3625

replace...is statutory, and not on whether the claimed subject matter is presently perceived to be an improvement over the prior art, e.g., whether it "enhances" the operation of a machine. *In re Toma* at 857.

In *Toma*, the claimed invention was a computer program for translating a source human language (e.g., Russian) into a target human language (e.g., English). The court found that the claimed computer implemented process was within the "technological art" because the claimed invention was an operation being performed by a computer within a computer.

The decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* never addressed this prong of the test. In *State Street Bank & Trust Co.*, the court found that the "mathematical exception" using the Freeman-Walter-Abele test has little, if any, application to determining the presence of statutory subject matter but rather, statutory subject matter should be based on whether the operation produces a "useful, concrete and tangible result". See *State Street Bank & Trust Co.* at 1374. Furthermore, the court found that there was no "business method exception" since the court decisions that purported to create such exceptions were based on novelty or lack of enablement issues and not on statutory grounds. Therefore, the court held that "[w]hether the patent's claims

Art Unit: 3625

are too broad to be patentable is not to be judged under §101, but rather under §§102, 103 and 112." See *State Street Bank & Trust Co.* at 1377. Both of these analysis goes towards whether the claimed invention is non-statutory because of the presence of an abstract idea. Indeed, *State Street* abolished the Freeman-Walter-Abele test used in *Toma*. However, *State Street* never addressed the second part of the analysis, i.e., the "technological arts" test established in *Toma* because the invention in *State Street* (i.e., a computerized system for determining the year-end income, expense, and capital gain or loss for the portfolio) was already determined to be within the technological arts under the *Toma* test. This dichotomy has been recently acknowledged by the Board of Patent Appeals and Interferences (BPAI) in affirming a §101 rejection finding the claimed invention to be non-statutory. See *Ex parte Bowman*, 61 USPQ2d (BNA) 1669 (BdPatApp&Int 2001).

Regarding claims 1-7, and 16: these claims fail to recited any non-trivial application of "technology" in the bodies of the claims. Certain "technology" is noted in these claims ("a user interface" (claim 1), for instance), however, such "technology" is not applied in any non-trivial manner. For example, the

Art Unit: 3625

steps involve merely the transfer of certain data, rather than the transformation of such data.

Regarding claim 17: this claim recites a program, per se. See MPEP 2106.

Regarding claim 19: this claim fails to recite a tangible result. The nature of carrier waves is transient and therefore provides no tangible result under the first prong of the test discussed above.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The recitation of a "use of a method", when interpreted as invoking a method of making an article of manufacture tangibly embodying the method according to claim 1 (i.e. a process which takes steps to embody the method according to claim 1 in the form of computer-executable code or instructions onto a computer-readable medium--thereby defining a process of making an article of manufacture in the form of a program product), fails to set forth any manipulative step which is performed in order to achieve the goal of the method. Accordingly, claim 16

Art Unit: 3625

fails to toll the statute because it does not define a statutory process pursuant to 35 USC 101.

Claim 16 is rejected under 35 U.S.C. 101 as being drawn to more than one statutory process.

The recitation of a "use of a method", when interpreted as invoking both a method of making an article of manufacture (i.e. a computer program product (see discussion above)) and a method of use (i.e. configuring a product), sets forth two distinct statutory processes. The language of 35 USC 101 identifies a "process" in the singular only. The processes, as per this interpretation, are not interrelated in the sense that the method of use (i.e. configuring a product) is not performed in performing a "use" which constitutes a method of making the article of manufacture (i.e. the computer program product). That is, one does not actually perform the steps recited in the method according to claim 1 in order to perform the "use" steps necessary for manufacturing a computer program product which results in an embodiment of the recited steps of the method according to claim 1 as computer-executable code or instructions for causing a computer to later perform the recited steps of the method according to claim 1. Accordingly, the two distinct

Art Unit: 3625

processes do not combine to form one statutory process within the purview of 35 USC 101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bienias (U.S. Patent No. 6,813,610).

Bienias discloses a method, system, program, program product, and data signal embodied in a carrier wave for configuring a product, where the product is to be assembled from a plurality of components, each component being available in at least one variant (see col. 1, lines 7-21).

In particular, the method comprises, *inter alia*, receiving inventory data from an inventory management system, the inventory data indicating an available subset of available

Art Unit: 3625

variants as being in stock; and indicating to the user, via a user interface, the available variants as being selectable (col. 1, lines 53-61; col. 3, lines 18-31; col. 4, lines 41-51).

Bienias further discloses, first and second pluralities of components each having a plurality of variants which are selectable (col. 2, lines 7-10; col. 4, lines 1-20).

Bienias further discloses graphically animating the positioning of the components relative to each other (col. 2, line 64-col. 2, line 1-10; col. 3, lines 57-67; col. 4, lines 21-30).

Bienias further discloses transmitting order information to a production management system. The order information includes configuration data identifying the selected variants (col. 5, lines 10-21; col. 5, lines 22-26).

The claims directed to a system (claims 8-15), a program (claim 17), program product (claim 18), and signal embodied in a carrier wave (claim 19) are written either in a parallel format to the method or rely upon the method. These claims are anticipated by Bienias for reasons similar to those discussed above with respect to the method claims.

Art Unit: 3625

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bienias (U.S. Patent No. 6,813,610).

Bienias does not disclose that the configurable products include a medical application device.

However, one of ordinary skill in the art would not have lost sight of the fact that Bienias' disclosure provides a greater teaching than the specifics related the particular type of products disclosed by Bienias. That is, the skilled artisan would have recognized the advantage of implementing the method of Bienias in configuring many types of products in which custom products, configurable by a user, are desired to be offered. Applicant's recitation of a medical application device provides nothing more than one of the many types of configurable products that the skilled artisan would have recognized as an obvious

Art Unit: 3625

variation of those already taught by Bienias and such modification of the Bienias method would have amounted to a change in degree (rather than a change in kind) of the method already disclosed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

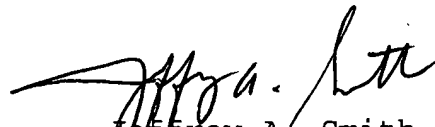
Palmer et al. (US 2002/0073001 A1) and Palmer et al. (US 2002/0107763) each disclose the configuration of a product which applications for determining availability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Smith whose telephone number is (571) 272-6763. The examiner can normally be reached on M-F 6:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Coggins can be reached on (571) 272-7159. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey A. Smith
Primary Examiner
Art Unit 3625

jas